

## Standard Operating Procedure: DUH Durham Campus: Restricted Antimicrobials SOP

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### Applicability:

- |   |   |
|---|---|
| <input type="checkbox"/> Ambulatory Surgery Center Arrington<br><input type="checkbox"/> Davis Ambulatory Surgery Center (DASC)<br><input type="checkbox"/> Duke Health Integrated Practice (DHIP)<br><input type="checkbox"/> Duke Health Lake Norman Hospital (DLNH)<br><input type="checkbox"/> Duke Health Technology Services (DHTS)<br><input type="checkbox"/> Duke HomeCare & Hospice (DHCH)<br><input type="checkbox"/> Duke Primary Care (DPC)<br><input type="checkbox"/> Duke Regional Hospital (DRH) | <input type="checkbox"/> Duke University Hospital (DUH) <span style="color: red;">(both campuses)</span><br><input checked="" type="checkbox"/> Durham Campus Only<br><input type="checkbox"/> Duke Raleigh Campus Only<br><input type="checkbox"/> Patient Revenue Management Organization (PRMO)<br><input type="checkbox"/> Population Health Management Office (PHMO) |
|---|---|

**Category Name:** DUH Durham Campus Only Restricted Antimicrobials

### 1. SCOPE/PURPOSE

Formulary restriction and preauthorization prior to dispensing for specified anti-infectives remain core strategies for antibiotic stewardship and is guideline-driven practice. This document details the criteria by which restricted antimicrobials are categorized and the standard operating procedure (SOP) by which these restrictions are implemented at DUH Durham Campus. This SOP includes processes for both pediatrics and adults. This SOP does not include processes for ambulatory settings.

### 2. REFERENCES

- a) DUH Durham ID Pager Numbers
  - 1) Infectious Disease – General ID: 970-4376
  - 2) Infectious Disease – Transplant ID: 970-7221
  - 3) Pediatric Infectious Disease (PEDS ID): 970-7420
  - 4) Pediatric Transplant Infectious Disease (PEDS Transplant ID): 206-9414
- b) CustomID website
- c) FormWeb website

### 3. RESPONSIBILITY

DUH Durham Campus clinicians ordering restricted antimicrobial agents, DUH Antimicrobial Stewardship and Evaluation Team (Duke ASET), DUH Durham Infectious Diseases (ID) Consultants (Adult and Pediatric), DUH Durham Clinical Pharmacy Coordinators, DUH Durham Assistant Chief Pharmacy Officer, DUH Durham Chief Pharmacy Officer.

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### 4. PROCEDURE

- 1) Infectious Diseases consultants should be contacted by ordering clinicians to obtain approval for restricted antimicrobials according to DUHS PMMC approved formulary and restriction status (**Table 1, Column 1**). Formulary information is also available on FormWeb and CustomID.

**Table 1. Agent Formulary Status and Restriction Type, Updated July 2026**

Formulary Status, Restriction Type	Agents with Overnight Approval Exception	Agents <i>without</i> Overnight Approval Exception (Approval Required Before Dose)
Formulary, Telephone/Chart review ID approval required  Requires a “Request for Restricted Antimicrobial Consult”	Ceftazidime Ertapenem Ganciclovir Fosfomycin Letermovir Meropenem Valganciclovir	
Formulary, ID consult approval required  Requires an Infectious Diseases Consult	Aztreonam/avibactam HIV medications HCV medications Ceftaroline Ceftobiprole Ceftazidime/avibactam Ceftolozane/tazobactam Daptomycin Imipenem Isavuconazole Micafungin Omadacycline Posaconazole Tedizolid Tigecycline Voriconazole	Bezlotoxumab Cefiderocol Cidofovir Colistin Dalbavancin Foscarnet Liposomal amphotericin B (Ambisome) Meropenem-vaborbactam Polymixin B
Non-formulary  Requires an Infectious Diseases Consult		All other non-formulary anti-infectives

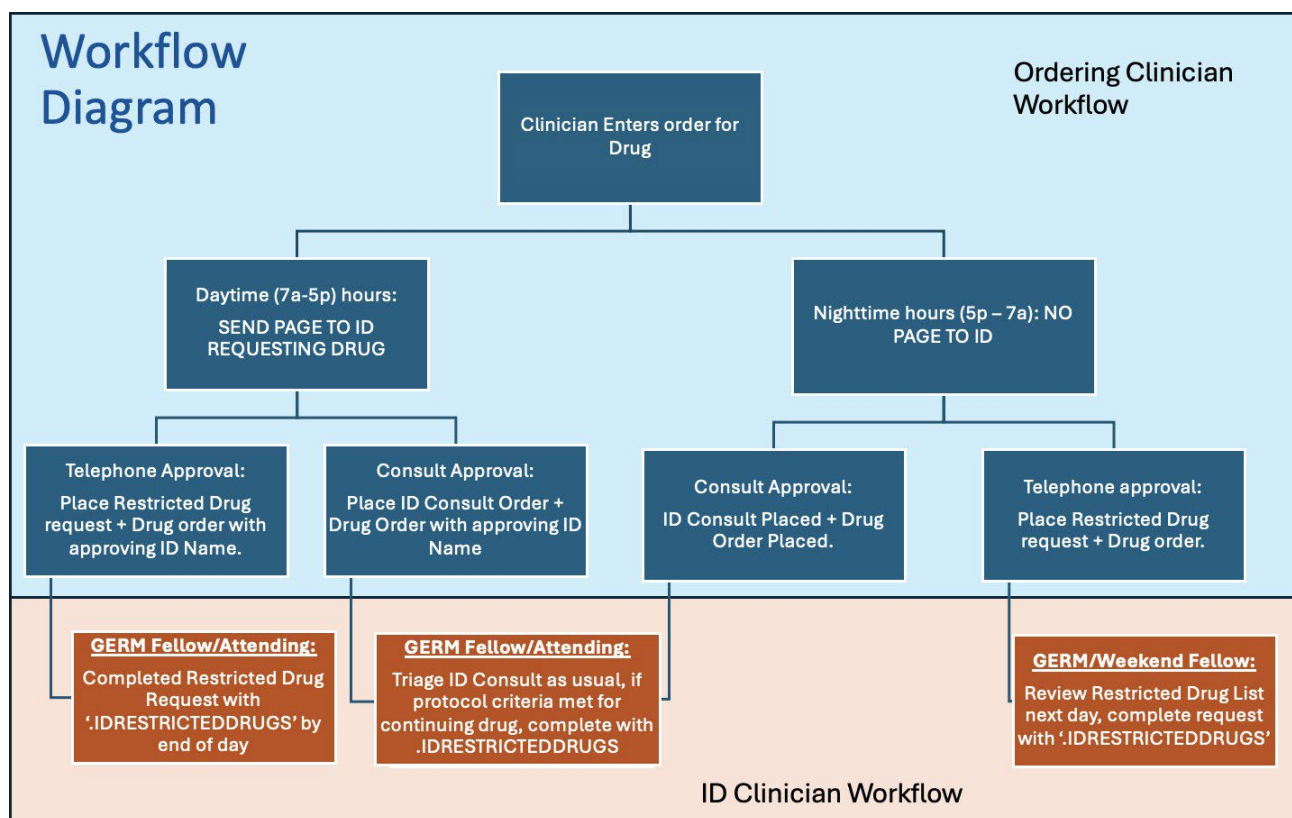
- 2) Per protocol exceptions outlined in DUH medication policy are outlined on CustomID, FormWeb, and incorporated into the order entry processes and LMAs for specific agents. For these specified

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indications and agents, ordering clinicians should select “Per Protocol” instead of listing the approving ID consultant’s name.

- 3) The process for obtaining ID approval for restricted agents is determined by the time of day and risk of the agent requested (See **Figure**). Orders for new starts of restricted agents that do not meet “Per Protocol” criteria, must be accompanied by either a Request for Restricted Antimicrobial Consult (for telephone/chart review agents) or an ID consult (**Table 1, Column 1**). These consult orders are incorporated in panels for restricted agents at all times of day.

**Figure: Process for obtaining ID approval for Restricted Agents**



- a) Daytime Process: Clinicians will page the appropriate ID team for prior approval either before or during order entry. Clinicians will indicate the name of the approving ID consultant in the order.
  - i) Telephone/Chart Review agents: ID consultants receiving Request for Restricted Antimicrobial Consult will document a chart note of the discussion and approval. Notes will be documented prior to 5pm on the day of request.
  - ii) ID Consult Required agents: ID consultants receiving ID Consult for restricted agents will complete a full bedside consult and document recommendations in consult notes within 24 hours of the request.

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- (1) Exception to Bedside ID Consult: ID consultants may provide approval via chart review note without a bedside encounter, for the continuation of therapy of ID consult restricted agents if patients meet the following criteria:
  - (a) The patient was seen at bedside, either inpatient or outpatient, by the Duke University Infectious Diseases service within the last 12 weeks.
  - (b) The indication for the restricted agent has not changed in the interim time period.
  - (c) The reason for inpatient admission is unrelated to the indication for the restricted agent, and there has been no clinical change and no concern for adverse drug events to warrant a repeat bedside evaluation.
  
- b) Overnight Process: Restricted anti-infective orders for new starts of restricted agents placed from 5 pm to 7 am also must be accompanied by a Request for Restricted Antimicrobial consult (telephone approval restricted agents only) or an ID consult as appropriate.
  - i) Agents with Overnight Exception (Table 1, Column 2): Most restricted anti-infectives may be ordered and dispensed overnight with plans for ID consultant review in the morning, by selecting “after hours (5p-7a), approval required next day” during order entry.
    - (1) ID consultants will review pending Requests for Restricted Antimicrobial Consults each morning, call requesting teams, then document their approval or alternative recommendations and follow up plans in a chart note (See **Appendix** for documentation instructions).
      - (a) Adult ID fellow assigned the GERM pager is responsible reviewing the ‘ID –Restricted Drugs’ list, resolving the Adult General requests, and notifying the Transplant ID fellow for review of transplant requests. The Transplant ID fellow will review and resolve requests for transplant patients.
      - (b) Pediatric ID fellow or faculty are responsible for reviewing and resolving requests from primary pediatric services.
  - ii) Agents without Overnight Exception (Table 1, Column 3): Some agents will not be verified or dispensed overnight without documentation of ID approval for the following reasons: non-formulary agents, high risk agents, agents where ID expertise is required to guide optimal use, or where overnight dosing is largely unnecessary (e.g. long-acting agent). If ordering clinicians feel overnight dosing is required due to the clinical scenario, they should page the appropriate ID consultant during off hours, discuss, and obtain approval with documentation of the approving ID consultant in the order. They should also place an ID consultation request to be completed the following morning.
  
- c) Pharmacists should verify orders for restricted agents with an approving ID consultant listed, “after hours (5p-7a), approval required next day,” or “per protocol,” as clinically appropriate. Doses may be verified prior to ID consult or telephone note documentation if verbal approval has been granted, indicated by the named approving ID consultant in the order.

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- i) If orders with “after hours (5p-7a), approval required next day” are being reviewed during daytime hours (e.g. after 7 am), pharmacists should not verify. Instead, they should contact the ordering clinician to request the order be replaced after ID approval has been obtained.
- 4) Active orders for restricted antimicrobials will be reviewed by a member of ASET each weekday morning to assure appropriate documentation and approvals have been obtained. Appropriate follow-up for ID consult or approval will be requested and documented for continued use. Alternative therapies will be discussed when necessary.
- 5) Cases in which the primary team and ID do not agree on approval will be escalated to the ASET Program Directors, or if necessary, the Chairs of DUH P&T and Children’s P&T or the Chief Pharmacy Officer, for review and resolution.

### 5. RELATED DOCUMENTS

- a) [DUH Antimicrobial Restriction Policy](#)
- b) [DUHS Antimicrobial Stewardship Policy](#)

### 6. ATTACHMENTS/FORMS -- Appendix

#### Appendix

#### **Instructions for Infectious Diseases Consultant Documentation of Telephone/Chart Review Agents:**

1. Review the **ID – Restricted Drugs** patient list. Review associated antimicrobial order for each patient, discuss with primary team to determine if restricted antimicrobial is appropriate, and the necessary follow-up steps.
2. Start a new “Consult” note type and assign the Restricted Antimicrobial Consult Order (Figure) Use the SmartPhrase .IDRESTRICTEDDRUGS. Cosigner should be the ID attending on service.
  - A detailed description in the follow up recommendation section should be included to ensure clear communication between the ID consultant, the primary team, and ASET (if applicable).

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My Note Tag Share w/ Patient Details

Type:  Service:

Date of Service:

Cosign Required

Please choose the associated consult orders:

Date/Time	Order Name	Unsuccessful Attempt	Provider
<input checked="" type="checkbox"/> 01/05/23 0652	Request for Overnight Antimicrobial		Yarring
<input type="checkbox"/> 12/31/22 1943	Consult to Interventional Radiology		Rychik,
<input type="checkbox"/> 12/27/22 2215	Consult to Nutrition Services		Vernola

Abbrev	Expansion
OVERNIGHTRESTRICTION	# ID Division - Documentation of reviewe...